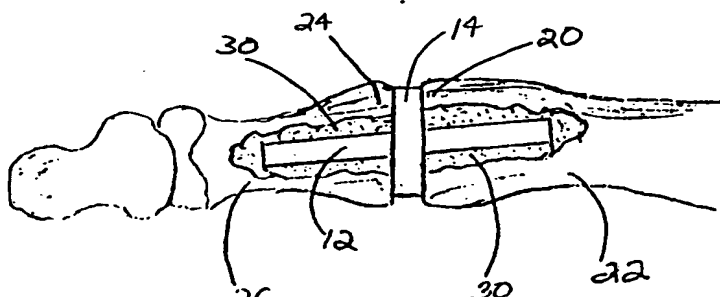




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<p>(21) International Application Number: PCT/US93/12215</p> <p>(22) International Filing Date: 15 December 1993 (15.12.93)</p> <p>(30) Priority Data: 07/990,415 15 December 1992 (15.12.92) US</p> <p>(71) Applicant: INTERNATIONAL POLYMER ENGINEERING, INC. [US/US]; 947 South 48th Street, Suite 127, P.O. Box 797, Tempe, AZ 85280-0797 (US).</p> <p>(72) Inventor: SKIBA, Jeffry, B.; 7250 South Kyrene Road, #358, Tempe, AZ 85283 (US).</p> <p>(74) Agent: ROSENBAUM, David, G.; Rosenbaum & Associates, 6991 East Camelback Road, Suite B-360, Scottsdale, AZ 85251 (US).</p>		<p>(81) Designated States: AU, BR, CA, JP, KR, NZ, PL, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: JOINT IMPLANT</p> <p>(57) Abstract</p> <p>A joint implant (10) is presented having an elongated cylindrical member (12) with an annular spacer (14) which accommodates the diameter of the cylindrical member by fitting loosely over the cylindrical member. The ends of the elongated cylindrical member are designed for insertion into the intramedullary canals (30) of adjacent bones while the annular spacer is designed to cushion the joint and maintain proper spacing between the bones.</p> 		

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JOINT IMPLANT

Background of the Invention

The present invention relates generally to a joint prosthesis. More particularly, the present invention relates to a joint implant designed to replace the inter-phalangeal or metatarsal-phalangeal joints in the foot, or the inter-phalangeal or metacarpal-phalangeal joints in the hand. In addition, the joint implant may be scaled up to replace any linear joint between adjacent long bones.

10 Joint implants for replacing finger and toe joints are well known. For example, U.S. Patent No. 4,246,662 describes a prosthetic joint comprising a one-piece body of flexible physiologically inert material having an enlarged central portion with two stem portions extending from opposite sides of the enlarged central portion. The enlarged central portion contains a slot which extends substantially through the central portion thereby forming a hinge for articulation of a joint. U.S. Patent No. 4,313,232 discloses an elastomeric joint prosthesis for replacing damaged joints in humans. The joint prosthesis is substantially elongate with oppositely tapered ends and a wider central segment. The joint prosthesis is made of a biocompatible cloth mesh which is reinforced with an elastomer to provide lateral stability and enable the prosthesis to flex along a single plane. Bending occurs along a plane in the wider central segment of the blank. U.S. Patent No. 4,634,445 describes a small joint spacing prosthesis having an elongate silicone rubber body which contains a Dacron or nylon string for reinforcement. The prosthesis further comprises a spherically shaped spacer in its middle having flat end faces for abutment with bone ends, and intramedullary stems extending from opposite sides of the spacer which are of lesser width than the spacer. The spacer and intramedullary stems comprise one continuous body. This patent also discloses that the bending of the joint prosthesis occurs in each of the stems and not in the spacer.

Therefore, there are no presently existing joint implants which form a structure comprising an elongated solid stem cylinder with a spacer which fits loosely over the cylinder thereby enabling the stem cylinder to flex during articulation of a joint at the point of the spacer, using the spacer as a fulcrum, but without substantial bending of the spacer.

Summary of the Invention

Accordingly, it is a principal object of the present invention to provide a joint implant.

10 It is a further object of the present invention to provide an inter-phalangeal joint implant designed to replace the inter-phalangeal or metacarpal-phalangeal joints in the foot, or the inter-phalangeal or metacarpal-phalangeal joints in the hand.

15 It is a still further object of the present invention to provide a joint implant for the hands and feet which can be scaled up to provide a joint implant to replace any linear joint between long bones.

20 It is yet a further object of the present invention to provide a joint implant which comprises a structure and composition which, during the articulation of a joint, affords uniform flexibility along the length of the joint implant.

25 It is still a further object of the present invention to provide a joint implant which comprises a structure and composition which forestall the implant from loosening at those points where it is anchored into the intramedullary canals of adjacent bones..

In brief, there is provided a joint implant which includes an elongated solid cylinder and an annular spacer.
30 The annulus of the spacer is of a size which accommodates the

diameter of the elongated solid cylinder with a loose fit. The ends of the elongated cylinder are implanted into the intramedullary canals of adjacent bones so that the spacer resides intermediate along the length of the cylinder and separates the distal and proximal ends of the bones to which the joint implant is attached. Both the solid cylinder and the annular spacer are made of expanded polytetrafluoroethylene (PTFE), which is a highly biocompatible material.

These and other objects, features and advantages of the present invention will become more apparent to those skilled in the art from the following more detailed description of the preferred embodiment taken with reference to the accompanying drawings.

Brief Description of the Drawings

FIG. 1 is a perspective view of a joint implant in accordance with the present invention.

FIG. 2 is a side elevational view of a joint implant in accordance with the present invention shown implanted in posterior and anterior ends of proximal and middle phalangeal bones, respectively.

Detailed Description of the Preferred Embodiment

Turning now to the preferred embodiment of the present invention with reference to Fig. 1, the joint implant 10 of the present invention consists primarily of an elongated solid cylinder 12 and an annular spacer 14. The annulus 16 of the annular spacer 14 is of a size which accommodates the diameter of the elongated solid cylinder 12 with a loose fit.

When the joint implant 10 is properly seated to replace a joint, its configuration allows the elongated solid cylinder

12 to flex at the point of the annular spacer 14 during the articulation of the joint without substantially bending the annular spacer 14. The annular spacer 14 is used as a fulcrum thereby enabling the elongated solid cylinder 12 to flex
5 uniformly along its length during joint articulation. The inventive joint implant 10 is advantageous over the joint implants described in the prior art in that the inventive joint implant 10 is able to impede the transference of stress resulting from joint articulation and thereby deter the joint
10 implant 10 from loosening at those positions where it is anchored in the intramedullary canals of adjacent bones.

Both the elongated solid cylinder 12 and the annular spacer 14 are preferably made of expanded polytetrafluoroethylene (PTFE), which is a biocompatible
15 thermoplastic polymer. Expanded PTFE comprises a porous microstructure of "nodes" and "fibrils". The fibers originate from the nodes with the nodes being generally thicker than the fibrils. The fibril length is controlled during processing and determines the porosity of the material.

20 PTFE is composed of long linear carbon chains surrounded by fluorine atoms. Expanded PTFE is hydrophobic as a result of the high electronegative charge of its polymer chains. Therefore, PTFE is less thrombogenic than other implant materials and virtually chemically inert.

25 Preferably, the joint implant is made of 100% PTFE, without additional copolymers, additives, or adhesives, thereby eliminating the possibility of leaching potentially bioreactive substances. Using 100% PTFE for the joint implant of the present invention is advantageous in that it provides
30 a chemically inert and biocompatible implant which has a high tensile strength and a low coefficient of friction. The expanded PTFE which comprises the joint implant promotes tissue incorporation and revascularization, and implant

anchoring. In addition, the pliability of the expanded PTFE provides the implant recipient with a comfortable fit.

Fig. 2 illustrates the joint implant 10 shown implanted in the posterior end 20 of the proximal phalanx 22 and the anterior end 24 of the middle phalanx 26 in the foot of a recipient. Although reference is made here to the anatomical positioning of the implant at an inter-phalangeal joint in the foot, it should be understood by those skilled in the art that the inventive joint implant 10 is capable of replacing many other joints between bones, including the metatarsal-phalangeal joints in the foot, the inter-phalangeal or metacarpal-phalangeal joints in the hand, and other linear joints between long bones.

The surgical implant procedure can be performed on an outpatient basis using intravenous sedation and local anesthesia. First, a dorsilinear incision is made over the inter-phalangeal joint. Next, a linear incision is made through the extensor tendon apparatus and joint capsule thereby exposing the proximal inter-phalangeal joint. Both the posterior end 20 of the proximal phalanx 22 and the anterior end 24 of the middle phalanx 26 are dissected from any attachments and transversely osteomized with bone fragments being promptly excised.

The intramedullary canals 30 of both the proximal phalanx 22 and the middle phalanx 26 are then reamed with a 4.0 wire-pass drill to approximately one-half their length. After the reamed intramedullary canals 30 are flushed with an antibiotic solution, the elongated solid cylinder 12, which is flexible due to its expanded PTFE composition, is inserted into the reamed intramedullary canal 30 of the proximal phalanx 22.

Next, an appropriately sized annular spacer 14 is selected and placed over the elongated solid cylinder 12. The diameter of the annular spacer 14 should approximate the

diameter of the proximal and middle phalanges 22, 26. That end of the elongated solid cylinder 16 which is exposed is then cut to fit the length of the reamed intramedullary canal 30 of the middle phalanx 26. The wound is closed following a visual check of the spacing and alignment of the joint.

Custom cutting the elongated solid cylinder 12 of the joint implant 10 at the time of surgery allows for the best fit in the reamed intramedullary canals, thereby providing flexibility in the joint while aligning the digits. The annular spacer 14 is designed to cushion the joint and maintain proper interdigit spacing.

After implantation of the joint implant 10, tissue ingrowth will occur in the node and fibril structure of the expanded PTFE of the elongated solid cylinder 12 which is located in the intramedullary canals of the bones. However, although the annular spacer 14 is also composed of expanded PTFE, the excised ends of the adjacent bones which abut the annular spacer 14 will not exhibit tissue ingrowth to the extent realized in the elongated solid cylinder 12 in that the ends of the bones feature less tissue growth activity. This enables the annular spacer 14 to function as a fulcrum thereby allowing the stress resulting from joint articulation to be distributed uniformly along a flexible length of the elongated solid cylinder 16, as previously described.

Clinical Studies

Nineteen patients received a total of thirty-six joint implants in accordance with the present invention over a three month period. Patients were selected based on adequate vascular status, presence of fibro-osseous unions (joint fusions), progressive joint deformity, and intolerable pain with little or no peripheral inter-phalangeal joint (PIPJ) range of motion available. The structural joint changes of those patients selected no longer responded to conservative

treatment. In addition, those patients with hammertoes often exhibited PIPJ subluxations/dislocations, often with various deformities.

The joint implant of the present invention was implanted
5 in patients according to the surgical procedure previously
described in the detailed description of the preferred
embodiment of the invention. A result of the clinical trials
showed patients with a significant digital re-alignment post-
operatively, with a shorter post-operative recovery period and
10 an earlier return to wearing normal footwear. The tests
further demonstrated minimal to non-existent post-operative
fibrositis, foreign body reaction, infection, and dislocation.
Patients also exhibited limited to non-existent post-operative
edema or pain. At twelve weeks, recipients of the inventive
15 joint implants demonstrated a functional range of motion,
stability, and good digital alignment.

While the preferred embodiment of the invention has been
shown and described, it will be apparent to those skilled in
the art that various changes and modifications may be made
20 without departing from the true spirit and scope of the
present invention. For that reason, the scope of the present
invention is set forth in the following claims.

I Claim:

- 1 1. A joint implant comprising:
2 a central stem member forming both distal and
3 proximal aspects of the joint implant wherein said central
4 stem member is substantially comprised of a material which
5 allows tissue ingrowth; and
6 an annular spacer having an annulus which
7 receives and accommodates the central stem member
8 therethrough, whereby said central stem member is free to
9 reciprocate in said annulus.

- 1 2. The joint implant according to Claim 1, wherein said
2 central stem member is uniformly flexible along a length of
3 the central stem member.

- 1 3. The joint implant according to Claim 2, wherein said
2 annular spacer is compressible thereby enabling stress
3 resulting from an articulation of a joint to be distributed
4 along a full length of said central stem member.

- 1 4. The joint implant according to Claim 3, wherein both
2 said central stem member and said annular spacer are
3 consisting essentially of expanded polytetrafluoroethylene.

- 1 5. A joint implant comprising:
2 an elongated cylinder having a uniform diameter
3 throughout and first and second ends which are inserted into
4 distal and proximal ends of adjacent bones, respectively, to
5 which the joint implant is attached; and
6 an annular spacer, having planar ends, which
7 accommodates said uniform diameter by fitting loosely over
8 said elongated cylinder such that when said joint implant is

9 inserted into said adjacent bones, said annular spacer resides
10 intermediate along a length of said elongated cylinder and
11 said planar ends of said annular spacer abut said adjacent
12 bones.

1 6. The joint implant according to Claim 5, wherein said
2 elongated cylinder is uniformly flexible along its length.

1 7. The joint implant according to Claim 6, wherein said
2 annular spacer is compressible thereby enabling stress
3 resulting from an articulation of a joint to be distributed
4 along a full length of said elongated cylinder.

1 8. The joint implant according to Claim 7, wherein both
2 said elongated cylinder and said annular spacer are consisting
3 essentially of expanded polytetrafluoroethylene.

1 9. A joint implant comprising:
2 a solid elongated cylinder consisting
3 essentially of expanded polytetrafluoroethylene, said solid
4 elongated cylinder having a uniform diameter throughout and
5 first and second ends which are inserted into distal and
6 proximal ends of adjacent bones, respectively, to which the
7 joint implant is attached; and
8 an annular spacer consisting essentially of
9 expanded polytetrafluoroethylene and having planar ends,
10 wherein said annular spacer accommodates said uniform diameter
11 of said solid elongated cylinder by slidably fitting over said
12 solid elongated cylinder such that when said joint implant is
13 inserted into said adjacent bones, said annular spacer resides
14 intermediate along a length of said solid elongated cylinder
15 and said planar ends of said annular spacer abut said adjacent
16 bones.

1 10. A method for implanting a joint implant between two
2 adjacent bones comprising:

3 inserting a first end of a central stem member
4 into an intramedullary canal of one of said two adjacent
5 bones;

6 placing an appropriately sized annular spacer
7 over said central stem member;

8 cutting a second end of said central stem
9 member to fit a length of an intramedullary canal of another
10 of said two adjacent bones such that said annular spacer
11 resides intermediate along a length of said central stem
12 member; and

13 inserting said second end of said central stem
14 member into said other of said two adjacent bones.

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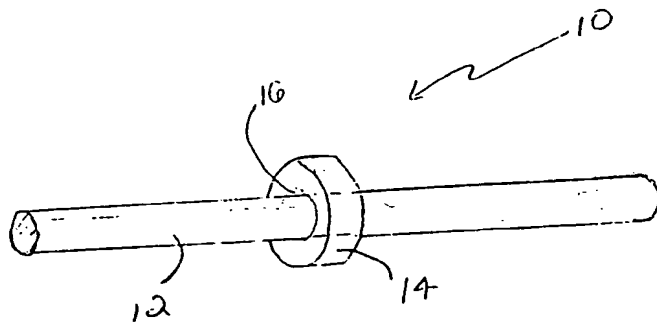


FIG. 1

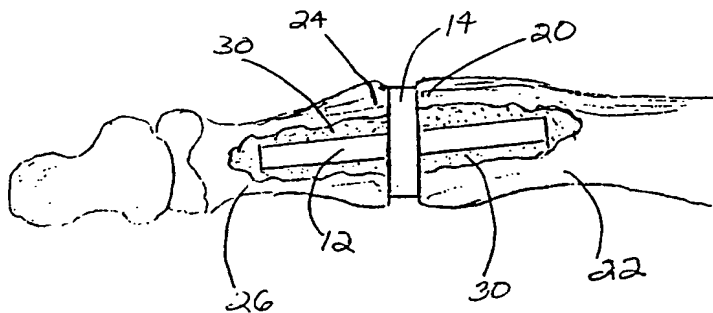


FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
CT/US93/12215

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61F 2/42

US CL : 623/21

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/11, 18, 16, 21

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,969,909, (Barouk), 13 November 1990. See Fig. 4, and column 2 lines 6-47.	1, 2, 10
Y	US, A, 5,098,779, (Kranzler et al.), 24 March 1992. See column 1, lines 53-58.	3, 4, 7, 8, 9
Y	US, A, 4,634,445, (Helal), 06 January 1987. See entire document.	5, 6, 7, 8, 9

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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